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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1615	

NOTIFICATION DATE	DELIVERY MODE
11/23/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/700,932	SCHINK ET AL.	
	Examiner	Art Unit	
	Isis A. Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *17 September 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26-32,34-39 and 56-72* is/are pending in the application.

4a) Of the above claim(s) *30,56-58 and 68-72* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27-29,31-39 and 59-67* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicants' amendment filed 09/17/2006; and foreign priority document filed 10/19/2007.

Claims 1-26, 33, 40-55 have been canceled, and claims 56-72 have been added.

Claims 27-32, 34-39, 56-72 are pending.

Election/Restrictions

1. Newly submitted claims 56-58 and 68-72 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: claims 68-72 are directed to two inventions that are distinct from the invention claimed by claims 27-32, 34-39, 56-67 (invention I). Claims 56-58 are directed to method of making the adhesive patch that have been previously withdrawn. Claims 68-71 are distinct from invention I as they do not require the specific active agent required by invention I. Claim 72 is distinct from invention I as it does not require the specific polyurethane required by invention I.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 56-58, 68-72 withdrawn from

consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim 30 has been previously withdrawn.

Claims 27-29, 31, 32, 34-39, 59-67 are included in the prosecution.

Priority

2. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

The following rejection has been overcome by virtue of applicants' amendment and remarks:

(A) The rejection of claims 36 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

(B) The rejection of claims 27, 28, 31, 36, 39 under 35 U.S.C. 102(b) as being anticipated by 4,839,174 ('174).

(C) All U.S.C. 103 (a) rejections based on US '174.

The following rejections ahs been discussed in the previous office action, and are maintained for reasons of record:

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 28 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claim has introduced new matter that is not described in the specification as originally filed. Claim 28 recites "the first side of the matrix substantially retains its original adhesive strength after application of the active ingredient". Nowhere in the original specification such limitation was found.

Response to Arguments

5. Applicant's arguments filed 09/17/2007 have been fully considered but they are not persuasive. Applicants are referring to table 2, example 7 for support for the limitation of "the first side of the matrix substantially retains its original adhesive strength after application of the active ingredient". Recourse the example 7 and table 2, applicants disclosed strong bond between the adhesive and a steel after application of polyurethane and not after application of the active ingredient. In accordance to MPEP

714.02, applicant should specifically point out to where in the disclosure a support for any amendment made to the claims can be found.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 27, 28, 31, 36, and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0 212 681 ('681).

EP '681 disclosed drug-releasing system comprised of a drug dispensing polyurethane matrix (abstract). The drug present in amount of 1-10% by weight of the matrix (co1.4, lines 50-51). The drug is dissolved in the matrix that further comprises permeation enhancer (col.5, lines 7-12). The polyurethane comprises hexamethylene diisocyanate and polyetherpolyol (col.7, lines 38-45). The adhesive characteristics of polyurethane as claimed by claims 27 and 28 are inherent. The reference does not disclose the polyurethane is foamed, therefore, the reference implied that the polyurethane is unfoamed.

Response to Arguments

8. Applicant's arguments filed 09/17/2007 have been fully considered but they are not persuasive. Applicants argue that the polyurethane disclosed by EP '681 is not self-

adhesive because the reference disclosed additional adhesive layers on the polyurethane layer. Applicants argue that the reference does not disclose the claimed polyurethane, and not all polyurethane are self-adhesives. Further, applicants argue that the reference does not disclose the active ingredients are applied to the preformed matrix or to a side thereof, but combined with the polyurethane matrix.

In response to these arguments, applicants' attention is drawn to the present claims that are directed to product, and all the elements of the product are disclosed by the reference. The incorporation of the active ingredients into the matrix as disclosed by the reference implies that some of the active ingredients is on the surface of the matrix. EP '681 teaches polyurethane absorbs water and dissolves the drug incorporated in the polyurethane (col.5, lines 40-46) leading to polyurethane matrix and dissolved drugs as instantly claimed. EP '681 disclosed polyurethane matrix made from polyetherpolyols and hexamethylene diisocyanate (second full paragraph of col. 7), therefore, the polyurethane disclosed by the reference is self-adhesive since compounds and their properties are inseparable. Furthermore, the additional adhesive layer disclosed by the reference is optional, implementing that the matrix itself is adhesive in absence of the skin contact adhesive.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over EP '681 in view of US 6,191,216 ('216).

The teachings of EP '681 are discussed as set forth in this office action.

Although EP '681 disclosed polyurethane comprising hexamethylene diisocyanate and polyetherpolyol, however, the reference does not explicitly teach the specific polyetherpolyol as claimed by claim 29.

US '216 teaches polyurethane gel composition that is preferred to use in medical applications because it is strongly self-adhesive and it is suitable for sticking to the skin in wound dressing (col.4, lines 45-57). The self-adhesive polyurethane gels comprises polyether polyols with 2 to 6 hydroxyl groups and having OH values of 20 to 112 and an

ethylene oxide content of ≥ 10 wt. %, and hexamethylene diisocyanate (col.2, lines 3-13).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide drug releasing system comprising polyurethane matrix comprising drug as disclosed by EP '681, and replace the polyurethane with the specific polyurethane gel disclosed by US '216 and comprising polyether polyols with 2 to 6 hydroxyl groups and having OH values of 20 to 112 and an ethylene oxide content of ≥ 10 wt. %, and hexamethylene diisocyanate, motivated by the teaching of US '216 that such a polyurethane gel composition is preferred to use in medical applications because it is strongly self-adhesive and suitable for sticking to the skin, with reasonable expectation of having drug releasing system comprising drug in polyurethane gel matrix comprising polyether polyols with 2 to 6 hydroxyl groups and having OH values of 20 to 112 and an ethylene oxide content of ≥ 10 wt. %, and hexamethylene diisocyanate that is strongly self-adhesive that sticks to the skin effectively.

Response to Arguments

12. Applicant's arguments filed 09/17/2007 have been fully considered but they are not persuasive. Applicants argue that EP '681 teaches oligomer cured by exposure to actinic radiation while polyurethane of US '216 is not an oligomer cured by actinic radiation, therefore there is no reason for one of ordinary skill in the art to employ polyurethane of US '216 instead of curable oligomer disclosed by EP '681.

In response to this argument, applicants' attention is directed to the scope of the present claims that is drawn to a product and all the element of the product are disclosed by the EP '681, except to the specific physical properties of the constituents of polyurethane, and the method of making the polyurethane using actinic radiation disclosed by EP '681 is not excluded by the present claims, and do not distinguish the presently claimed product over the product of the prior art. EP '681 disclosed oligomer made from the reaction of diisocyanate with glycol (col. 4, lines 29-30 of EP '681). EP '681 teaches the generic constituents of the polyurethane, and US '216 teaches the species of the polyurethane that is made of polyether polyols with 2 to 6 hydroxyl groups and having OH values of 20 to 112 and an ethylene oxide content of ≥ 10 wt. %, and hexamethylene diisocyanate, and further teach such polyurethane is preferred to use in medical applications because it is strongly self-adhesive and suitable for sticking to the skin. Therefore, one having ordinary skill in the art would have been motivated to replace polyurethane disclosed by EP '681, whether cured by actinic exposure or not, whether oligomer or polymer, by polyurethane polymer disclosed by US '216 because US '216 teaches such a polyurethane as a preferred self adhesive to use in medical applications because it is strongly self-adhesive and suitable for sticking to the skin. US '216 is an analogous art, and is in the field of applicant's endeavor or, and reasonably pertinent to the particular problem with which the applicant was concerned, therefore, it is reasonable to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). Furthermore, there is a reasonable expectation of success of obtaining drug releasing system comprising drug

in polyurethane gel matrix comprising polyether polyols with 2 to 6 hydroxyl groups and having OH values of 20 to 112 and an ethylene oxide content of ≥ 10 wt. %, and hexamethylene diisocyanate that is strongly self-adhesive that sticks to the skin effectively. A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the claims would have been prima facie obvious within the meaning of 35 U.S.C. 103 (a).

13. Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over EP '681 in view of US 6,399,092 ('092).

The teachings of EP '681 are discussed as set forth in this office action.

However, the reference does not teach that the polyurethane matrix comprises superabsorbent as claimed by claim 32.

US '092 teaches wound dressing superabsorbent polymer and active ingredient that when applied to the skin the superabsorbent absorbs fluid and slowly releases the active agent into the skin (abstract).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide drug releasing system comprising drug in polyurethane matrix as disclosed by EP '681, and further add superabsorbent to the

drug containing matrix as disclosed by US '092, motivated by the teaching of US '092 that when superabsorbent is added to the drug containing matrix it absorbs fluid from the skin and slowly releases the active agent into the skin, with reasonable expectation of having drug releasing system comprising polyurethane matrix containing drug and superabsorbent that absorbs fluid from the skin and slowly releases the active agent into the skin, hence enhancing the drug release to the skin.

Response to Arguments

14. Applicant's arguments filed 09/17/2007 have been fully considered but they are not persuasive. Applicants argue that EP'681 requires water for the functioning of the delivery system. Accordingly, the presence of a superabsorbent in this system would be harmful in that the superabsorbent can be expected to absorb the water that is needed for dissolving the drug inside the matrix and for transporting it from inside the matrix to the skin. Accordingly, there is no reason for one of ordinary skill in the art to incorporate a superabsorbent into the drug delivery system according to EP'681 and such a combination would not result in the subject matter of dependent claim 32.

In response to this argument, it is argued that EP '681 desired water absorption in order to release the active ingredients (col.5, lines 40-47), and US '092 teaches inclusion of superabsorbent polymer with the polymer composition forming wound dressing for slowly release of active ingredients (abstract; col.4, lines 31-38). Water absorption is desired by EP '681, and this would motivate one having ordinary skill in

the art to look for superabsorbent disclosed by US '092 especially that US '092 teaches matrix comprising superabsorbent absorbs fluid from the skin and slowly releases the active agent into the skin, as desired by EP '681. US '092 is an analogous art, and is in the field of applicant's endeavor or, and reasonably pertinent to the particular problem with which the applicant was concerned, therefore, it is reasonable to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). Furthermore, there is a reasonable expectation of having drug releasing system comprising polyurethane matrix containing drug and superabsorbent that absorbs fluid from the skin and slowly releases the active agent into the skin, hence enhancing the drug release to the skin. A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the claims would have been prima facie obvious within the meaning of 35 U.S.C. 103 (a).

15. Claims 33, 35, 38, 39, 62 and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP '681 in view of US 5,866,157 ('157).

The teachings of EP '681 are discussed as set forth in this office action.

Although EP '681 suggested analgesics and anesthetics among other drugs suitable to be delivered in the polyurethane matrix, however, the reference does not specifically teach active agents recited by claim 33 or the essential oils claimed by claim 35. The reference does not teach the specific enhancers disclosed by claim 38 or the thickness of the matrix as claimed by claim 39.

US '157 teaches patch formulation for delivering active agent to the skin that has increase percutaneous absorption of the drugs with extremely reduced skin irritation (abstract). The formulation comprises permeation enhancers including isopropyl myristate and menthol, which is an essential oil (col.5, lines 11, 14). The active agents included lidocaine (col.3, line 33). The active ingredients is present in an amount of 0.1-20% (abstract). The examples showed that the drug containing layer having thickness of 100 μm.

Therefore, US '157 showed that lidocaine is known to be delivered to the skin in skin patches, and one having ordinary skill in the art would have used lidocaine in the matrix disclosed y EP '681. The references also showed that such thickness of the drug containing layer as claimed has been used in the art.

Accordingly, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide drug releasing system comprising polyurethane matrix comprising drug and permeation enhancer as disclosed by EP '681, and replace the permeation enhancer with isopropyl myristate and menthol as disclosed by US '157, motivated by the teaching of US '157 that transdermal formulation comprising such enhancer has increase percutaneous absorption of the drugs with extremely reduced

skin irritation, with reasonable expectation of having drug releasing system comprising polyurethane matrix comprising drug, myristate and menthol providing increased percutaneous absorption and extremely reduced skin irritation at the site of application.

16. Claims 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP '681 in view of US 6,630,442 ('442).

The teachings of EP '681 and US '174 are discussed as set forth in this office action.

However, the references do not specifically teach dexpanthenol as an active agent as claimed by claims 33 and 34.

US '442 teaches composition comprises dexpanthenol that repairs and reduces skin damage because it is quick and deep penetrating moisturizer (abstract; col.23, lines 38-42).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide polyurethane matrix drug comprising drug as disclosed by any of EP '681 or US '174, and replace the drug with dexpanthenol or further add dexpanthenol to the matrix as disclosed by US '442, motivated by the teaching US '442 that dexpanthenol repairs and reduces skin damage because it is quick and deep penetrating moisturizer, with reasonable expectation of having polyurethane matrix comprising drug and/or dexpanthenol that repairs and reduces skin damage effectively.

17. Claim 33, 35, 64 and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP '681 in view of EP 1 059 032 ('032).

The teachings of EP '681 are discussed as set forth in this office action.

However, the reference does not specifically teach essential oils as active ingredient as claimed by claims 33 and 35.

EP '032 teaches essential oils including menthol are preferred topical disinfectant because of the advantage of imparting pleasant odor to the disinfecting composition (paragraphs 0035, 0036). Essential oils are present in an amount of 0.001-5% (paragraph 0037).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide polyurethane matrix comprising drug as disclosed by EP '681, and replace the drug with essential oil including menthol as disclosed by EP '032, motivated by the teaching of EP '032 that essential oils including menthol are preferred topical disinfectant because of the advantage of imparting pleasant odor to the disinfecting composition, with reasonable expectation of having polyurethane matrix comprising menthol that has disinfecting effect and further impart pleasant odor to the matrix.

Response to Arguments

18. Applicant's arguments filed 09/17/2007 have been fully considered but they are not persuasive. Applicants argue that one having ordinary skill in the art would not e motivated to combine EP '681 with any of US '157, US '442 or EP 032 because the

references fail to cure the deficiency of EP '681 by disclosing matrix as claimed by claim 27 produced by applying active agent in liquid dissolved form to he side of already made polyurethane matrix.

In response to these arguments, and in considering the disclosure of the reference, it is proper to take into account not only the specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom. *In re Preda*, 401 F.2d 825, 826, 159 USPQ 342, 344 (CCPA 1968). The rational to modify or to combine the prior art does not have to be expressly stated in the prior art; the rational may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art. The reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve different problem. It is not necessary that the prior art suggest the combination or modification to achieve the same advantage or result discovered by applicant. *In re Linter*, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972). US '157, US '442 or EP 032 are relied upon for the solely teaching that such active ingredients are suitable for topical or transdermal delivery. A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the claims would have been prima facie obvious within the meaning of 35 U.S.C. 103 (a).

The following new ground of rejections are necessitated by applicants' amendment:

19. Claim 59 is rejected under 35 U.S.C. 103(a) as being unpatentable over US '861 in view of US 6,183,770 ('770).

The teachings of EP '681 are discussed under 102 rejection as set forth in this office action.

Although EP '681 teaches drug is incorporation of the active ingredients into the matrix as disclosed by the reference implies that some of the active ingredients is on the surface of the matrix, however, the reference does not explicitly teach the application of the active ingredient on the surface of the adhesive, which step is directed to the method of making the device.

US '770 teaches patch for delivering agents to the skin comprises a pad, having an upper and lower surface area, and an adhesive adhered on the lower surface area of the pad and an active agent for delivery to the skin is applied to the patch in a manner such that the deleterious effects of the adhesive on the active agent are minimized (col.1, line 63 till col.2, line 3).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide transdermal patch comprising polyurethane matrix incorporating drug as disclosed by EP '681, and add active agent on the skin contacting surface of the polyurethane matrix instead of incorporating the drug into the matrix as disclosed by US '770, motivated by the teachings of US '770 that such a structure of the patch minimizes the deleterious effects of the adhesive on the active , with reasonable expectation of having transdermal patch comprising polyurethane matrix with drug/active agent is applied to the skin contact surface of the matrix wherein the deleterious effects of the adhesive on the active agent are successfully minimized.

20. Claims 62-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP '681 in view of US 6,698,162 ('162).

The teachings of EP '681 are discussed under 102 rejection as set forth in this office action.

Although EP '681 teaches local anesthetic and anti-inflammatory drugs to be incorporation into the matrix, however, the reference does not explicitly teach specific species of drugs as instantly claimed by claims 62-65.

US '162 teaches transdermal application of drugs including lidocaine, nonivamide, capsaicin, and menthol, and teaches the durability of such drugs when the topical formulation is sterilized (abstract; col.4, lines 25-32).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide transdermal patch comprising polyurethane matrix

incorporating local anesthetic and anti-inflammatory drugs as disclosed by EP '681, and replace the active agent with one of species of local anesthetic and anti-inflammatory disclosed by US '162, motivated by the teaching of US '162 that such drugs are durable when the topical formulation is sterilized, with reasonable expectation of having transdermal patch comprising polyurethane matrix including one of lidocaine, nonivamide, capsaicin, and menthol that are successfully durable for sterilization when such a process is needed.

21. Claims 60-61, 65-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP '681 in view of US 5,985, 860 ('860).

The teachings of EP '681 are discussed under 102 rejection as set forth in this office action.

Although EP '681 teaches anti-inflammatory drugs to be incorporation into the matrix, however, the reference does not explicitly teach specific species of drugs as instantly claimed by claims 60-61 and 65-66.

US '860 teaches transdermal composition for reliving pain while alleviating side effects caused by systemic administration. The composition comprises NSAIDs including ibuprofen, salicylic acid, capsaicin, and methyl nicotinate (abstract; col.2, lines 1-7; col.3, lines 31-36).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide transdermal patch comprising polyurethane matrix incorporating anti-inflammatory drugs as disclosed by EP '681, and replace the active

agent with one of species anti-inflammatory disclosed by US '860, motivated by the teaching of US '860 that transdermal application of such drugs relieves pain while alleviating side effects caused by systemic administration, with reasonable expectation of having transdermal patch comprising polyurethane matrix including one of ibuprofen, salicylic acid, capsaicin, and methyl nicotinate to be delivered transdermally without causing unwanted systemic side effects.

Conclusion

22. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis A Ghali
Primary Examiner
Art Unit 1615

IG

Isis Ghali

ISIS GHALI
PRIMARY EXAMINER